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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/575,063

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Robert J Harman

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SEED INTELLECTUAL PROPERTY LAW GROUP PLLC

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EXAMINER

BARNHART, LORA ELIZABETH

ART UNIT

PAPER NUMBER

1651

MAIL DATE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/575,063	Applicant(s) HARMAN ET AL.	
	Examiner Lora E. Barnhart	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 January 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,20-23,32,37,80 and 96 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,20-23,32,37,80 and 96 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendments

Applicant's amendments filed 1/28/10 to claims 1-3, 20-23, 32, 80, and 96 have been entered. Claim 38 has been canceled in this reply. No claims have been added in this reply. Claims 1-3, 20-23, 32, 37, 80, and 96 remain pending in the current application, all of which are being considered on their merits. References not included with this Office action can be found in a prior action. Any rejections of record not particularly addressed below are withdrawn in light of the claim amendments and applicant's comments.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 20-23, 32, 37, 80, and 96 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1 and 21 are drawn to methods of preparing populations comprising stem cells; each uses adipose tissue as a starting material. Both methods require processing the adipose tissue starting material "to separate the cells therein from lipids," thereby yielding a cell population that contains stem cells. However, the specification does not

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describe such a method adequately to comply with the requirements of 35 U.S.C. § 112, first paragraph.

Adipose tissue comprises cells that contain stored lipid (adipocytes). The lipid is stored within fat droplets within each adipocyte. See Fellner, U.S. Patent 5,143,063; reference A; at column 1, lines 12-17. In other words, lipid is an integral part of the cells that make up adipose tissue. Adipose tissue does not contain free-floating extracellular lipids. Separating adipose cells from lipid can be accomplished by homogenizing adipose and then extracting the lipids using nonpolar solvents such as chloroform and methanol; see Folch et al., 1957, *Journal of Biological Chemistry* 226: 497-509; reference U; at pages 497-498. However, methods like Folch's separate lipids at the expense of the cell. The specification does not provide any guidance for carrying out the method as claimed. The specification includes a general statement at page 13, lines 12-14, that cells may be separated from lipids, but the working examples do not clearly point out any step that accomplishes this end. Generic language in the specification, even generic language that explicitly recites a claim limitation, does not automatically satisfy the written description requirement. See *Ariad Pharm. Co. v. Eli Lilly & Co.*, 94 U.S.P.Q.2d 1161, 1171-72 (Fed. Cir. 2010). Here, the claims appear to be drawn to an impossible method, so the fact that the specification merely mentions the separation of lipids in passing cannot fulfill the description requirement.

Claims 32 and 96 appear to be broader than claims 1 and 21, but they employ identical steps (other than the starting product). However, they suffer the same deficiencies. The "collagen-based tissue" may be adipose tissue, in which case the

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above reasoning applies. Claim 37 allows that the starting material may be "umbilical cord matrix," which does not appear to contain lipid, according to a thorough search of the art. It is not clear how the processing step of claims 32 and 96 can be carried out on a starting material that does not initially contain lipids, and the specification does not describe a method of separating lipids from a lipid-free tissue.

Claim 80 is similar to claim 96 but requires that the processing of step (b) include contacting the starting material with "an array of screens," such that the stem cells (presumably those in the starting material) are not isolated from any other cells purified in step (c), i.e. a later step.

The specification details a method in which a fat sample is obtained from a mammal, drained, minced, digested with collagenase, and rinsed several times, "depending on how bloody the sample is." See page 23, lines 25-26. Blood is a cell type; the exemplified method appears to separate stem cells at least from blood cells. The working example also refers to "any remaining fat particles" at step (i), but it is not clear whether these "fat particles" are "pieces of adipose tissue" or "globules of lipid." There appears to be no step within the exemplified method that removes cells from lipid.

The specification does not clearly describe the claimed method. This rejection might be overcome if applicant could particularly point out the basis for each claimed step.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 1-3, 20-23, 32, 37, 80, and 96 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The language of a claim must make it clear what subject matter the claim encompasses to adequately delineate its "metes and bounds." See, e.g., *In re Hammack*, 427 F.2d. 1378, 1382, 166 USPQ 204, 208 (CCPA 1970); *In re Venezia* 530 F.2d. 956, 958, 189 USPQ 149, 151 (CCPA 1976); *In re Goffe*, 526 F.2d. 1393, 1397, 188 USPQ 131, 135 (CCPA 1975); *In re Watson*, 517 F.2d. 465, 477, 186 USPQ 11, 20 (CCPA 1975); and *In re Knowlton*, 481 F.2d. 1357, 1366, 178 USPQ 486, 492 (CCPA 1973). The courts have also indicated that before claimed subject matter can properly be compared to the prior art, it is essential to know what the claims do in fact cover. See, e.g., *In re Steele*, 305 F.2d. 859, 134 USPQ 292 (CCPA 1962); *In re Moore*, 439 F.2d. 1232, 169 USPQ 236 (CCPA 1969); and *In re Merat*, 519 F.2d. 1390, 186 USPQ 471 (CCPA 1975). In this case, the claims are so indefinite as to preclude a substantive search by the examiner.

Claims 1 and 21 are drawn to methods that require first "obtaining adipose tissue," then processing it "to separate the cells therein from lipids," thereby yielding "a purified cell preparation comprising . . . stem cells." As discussed above, the lipid contained in adipose tissue is all found inside the cells; removing the lipid from the adipose tissue would require lysing the cells, i.e. destroying the stem cells. It is not clear how lipid can be separated from cells found in adipose tissue without removing the stem cells. Clarification is required.

Because claims 2, 3, 20, 22, and 23 depend variously from indefinite claims 1 and 21 and do not clarify the point of confusion, they must also be rejected under 35 U.S.C. 112, second paragraph.

Claims 32, 80, and 96 require beginning with a “collagen-based tissue,” then separating the cells therein from lipids, which is confusing because there is no requirement that the collagen-based tissue contain lipids. The scope of the “processing” step in each claim cannot be determined. Claim 37 is further queried, since it is not clear that umbilical cord matrix contains lipids.

It is not clear whether the “device comprising an array of screens” in claim 80 separates the cells from the lipid or whether it serves some other purpose.

Response to Arguments

Applicants’ comments regarding the rejections of record have been considered as they pertain to the new rejections, but they are not persuasive. None of the comments particularly points out basis for claiming the instant methods. The declaration under 37 C.F.R. 1.132 submitted 1/28/10 by Jeffrey Catania (hereafter “the Catania declaration”) has also been considered, but it is not persuasive of error. The Catania declaration refers to numerous steps that are not in the instant claims (e.g., mincing, enzymatic digestion) and does not indicate which step in the original specification corresponds to the “removal of lipid” as in paragraph 3 of the declaration. The Catania declaration appears to include a step in which some cells are lysed, but the instant claims are not so limiting, and they clearly require that no cells be separated from the desired stem cells.

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lora E. Barnhart whose telephone number is (571)272-1928. The examiner can normally be reached on Monday-Thursday, 9:00am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lora E Barnhart/
Primary Examiner, Art Unit 1651